

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SEPRACOR, INC.,	)	
	)	
Plaintiff, Counterclaim-	)	
Defendant,	)	C.A. No. 06-113-KAJ
	)	
v.	)	
	)	
DEY, L.P. AND DEY, INC.,	)	
	)	
Defendants, Counterclaim-	)	
Plaintiffs.	)	

**DEY’S OPENING MEMORANDUM IN SUPPORT OF ITS  
MOTION TO STRIKE PLAINTIFF’S CLAIM FOR WILLFUL INFRINGEMENT**

**I. PRELIMINARY STATEMENT**

Pursuant to Rule 12(f) of the Federal Rules of Civil Procedure, Defendants Dey, L.P. and Dey, Inc. (collectively “Dey”) respectfully submit this opening memorandum in support of its Motion to Strike Plaintiff’s Allegations Concerning Willful Infringement.

The single issue raised in this motion is whether Sepracor’s allegation that Dey filed an ANDA with an objectively baseless Paragraph IV certification is sufficient as a matter of law to support a claim of willful infringement. This Court previously has specifically rejected the proposition that a claim for willful infringement may be premised on allegations, such as those made by Sepracor in this case, that the ANDA applicant filed a “baseless” paragraph IV certification. Accordingly, Dey respectfully requests this Court to strike Sepracor’s willfulness claim.

## II. FACTUAL BACKGROUND

Pursuant to the Hatch-Waxman Act, Dey filed ANDA No. 77-800 seeking approval to market its levalbuterol hydrochloride inhalation solutions in three different concentrations: 0.31 mg/3 ml, 0.63 mg/3 ml and 1.25 mg/3 ml (“levalbuterol hydrochloride solutions”). Dey’s ANDA was filed with a Paragraph IV certification stating that Dey believes the patents Sepracor listed in the Orange Book as claiming the Sepracor brand levalbuterol hydrochloride solution, known as Xopenex® or a method of using Xopenex®, are either invalid or not infringed by Dey’s levalbuterol hydrochloride solutions. 21 U.S.C. §355(j)(2)(B)(iii). Dey notified Sepracor that it had filed an ANDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(B). Sepracor filed this action (suing Dey on 5 of the 6 patents) within 45 days of receiving the certification notice so as to affect a 30 month stay of ANDA approval. 21 U.S.C. §355(j)(5)(B)(iii).

In its complaint, Sepracor alleges that Dey’s Paragraph IV certification is “devoid of an objective good faith basis in either the facts or the law.” (D.I. 1, ¶ 25.) Sepracor contends that in filing its ANDA No. 77-800 to obtain approval to engage in the commercial manufacture, use and/or sale of its Levalbuterol Inhalation Solutions, Dey’s actions are and continue to be “willful and deliberate.” (D.I. 1, ¶ 26.) Sepracor also seeks a judgment that Dey’s alleged infringement is willful. (D.I. 1, ¶ D.)

During a telephone conference in August 2006, counsel for Sepracor informed counsel for Dey that Sepracor wanted to enter into a joint stipulation to withdraw Sepracor’s willfulness allegations without prejudice. Consistent with that telephone call, in response to an interrogatory requesting the basis for Sepracor’s allegations of willfulness, Sepracor responded “the parties are discussing Sepracor’s withdrawal, without prejudice, of its claim for willfulness.” (D.I. 41, Response to Interrogatory No. 13 served on August 28, 2006.) In a letter dated October 20,

2006, however, Sepracor's counsel implicitly withdrew its offer to enter into a stipulation to withdraw its claims of willful infringement. "Dey's willfulness is a basis for exceptional case. However, in the interest of efficiency ... we are working on a draft proposal for a joint stipulation, without prejudice, to stay discovery for exceptional case until such time as there is a prevailing party." (Letter from S. Dadio to E. Leff dated October 20, 2006).

### III. ARGUMENT

Federal Rule of Civil Procedure 12(f) states that a "court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "The function of a 12(f) motion to strike is to avoid expenditure of time and money that necessarily arises from litigating spurious issues by disposing of issues prior to trial." *Del. Health Care, Inc. v. MCD Holding Co.*, 893 F. Supp. 1279, 1291 (D. Del. 1995). As detailed below, Sepracor's allegations of willfulness are insufficient as a matter of law and should be stricken.

#### A. SEPRACOR'S WILLFULNESS ALLEGATIONS ARE FORECLOSED BY CLEAR FEDERAL CIRCUIT PRECEDENT

The Federal Circuit has held that the mere filing of an Abbreviated New Drug Application ("ANDA") cannot sustain a finding of willful infringement. *Glaxo Group Ltx. v. Apotex, Inc.*, 376 F.3d 1339, 1351-52 (Fed. Cir. 2004). In *Glaxo* the Federal Circuit explained that 35 U.S.C. § 271(e)(2) treats the filing of an ANDA as a "highly artificial" act of infringement and therefore "the mere filing of an ANDA cannot constitute grounds for a willful infringement determination." 376 F.3d at 1349 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)). The statute creates that "technical" act of infringement "for purposes of establishing jurisdiction in federal courts," because the ANDA applicant has "not yet infringed the patents at issue." *Id.* at 1351. As a result, the Federal Circuit concluded it is legal error to

permit a finding of willful infringement where, as here, the only act of infringement is the filing of an ANDA. *Id.*

**B. THIS COURT HAS REJECTED THE ARGUMENT THAT WILLFUL INFRINGEMENT MAY REST ON ALLEGATIONS THAT AN ANDA APPLICANT FILED A BASELESS PARAGRAPH IV CERTIFICATION**

As recently as July 6, 2006, this Court held that the weight of case law and other authority supports finding that “an ANDA filing and accompanying paragraph IV certification cannot support a charge of willful infringement.” *Boehringer Ingelheim Intern. GMBH v. Barr Labs., Inc.*, No. 05-700, 2006 WL 1876918, at \*2 (D. Del. Jul. 6, 2006). In *Boehringer*, this Court addressed the precise allegations Sepracor asserts here. The patentee in *Boehringer* asserted that defendants’ infringement was willful because the ANDA applicant filed an ANDA containing a paragraph IV certification. *Id.* at \*1. This Court rejected the argument citing the “more recent and growing weight of authority” which hold that the mere filing of an ANDA cannot support a claim for willful infringement. *Id.* at \*2 (citing *UCB Societe Anonyme v. Mylan Labs., Inc.*, No. 04-683, 2006 WL 486895, at \*2 (N.D. Ga. Feb.28, 2006) (“Applying Glaxo ..., [plaintiffs] allegations cannot support a claim of willful infringement.”); *Celgene Corp v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006) (“The Glaxo case makes clear that the Hatch-Waxman Act exists ... to permit the matter [of infringement] to be decided before the drug goes to market and an actual, rather than artificial, act of infringement occurs.”); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 409 F. Supp. 2d 722, 729 (E.D. Va. 2006) (“[T]he fact that the appellate court in Glaxo emphasizes that the purpose of the ANDA process is to create an ‘artificial’ act of infringement for jurisdictional purposes strongly supports this Court’s conclusion that even a baseless ANDA filing may never constitute willful infringement.”))

Sepracor’s Complaint contains no allegations which would support a finding of willful

infringement. The only alleged act of infringement in the Complaint is Dey's filing of an ANDA with a Paragraph IV certification. As a matter of law, these allegations cannot support a finding of willfulness. Accordingly, Sepracor's allegations of willful infringement should be stricken under Fed. R. Civ. P. 12(f).

#### IV. CONCLUSION

For the foregoing reasons, Dey respectfully requests that this Court strike the allegations concerning willful infringement in paragraphs 25 and 26, along with paragraph lettered "D" in Sepr

ASHBY & GEDDES

*/s/ John G. Day*

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Steven J. Balick (I.D. # 2114)  
John G. Day (I.D. # 2403)  
Tiffany Geyer Lydon (I.D. # 3950)  
222 Delaware Avenue, 17th Floor  
P.O. Box 1150  
Wilmington, Delaware 19899  
Telephone: (302) 654-1888  
Fax: (302) 654-2067  
[sbalick@ashby-geddes.com](mailto:sbalick@ashby-geddes.com)  
[jday@ashby-geddes.com](mailto:jday@ashby-geddes.com)  
[tlydon@ashby-geddes.com](mailto:tlydon@ashby-geddes.com)

*Of Counsel:*

Edward H. Haug  
Kimberly J. McGraw  
FROMMER LAWRENCE & HAUG LLP  
745 Fifth Avenue  
New York, New York 10151  
Telephone: (212) 588-0800  
Fax: (212) 588-0500

Elizabeth A. Leff  
FROMMER, LAWRENCE & HAUG LLP  
1667 K Street, N.W.  
Washington, D.C. 20006  
Telephone: (202) 292-1530  
Fax: (202) 292-1531

Dated: November 7, 2006  
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**CERTIFICATE OF SERVICE**

I hereby certify that on the 7<sup>th</sup> day of November, 2006, the attached **DEY'S OPENING MEMORANDUM IN SUPPORT OF ITS MOTION TO STRIKE PLAINTIFF'S CLAIM FOR WILLFUL INFRINGEMENT** was served upon the below-named counsel of record at the address and in the manner indicated:

Richard D. Kirk, Esquire  
The Bayard Firm  
222 Delaware Avenue, Suite 900  
P.O. Box 25130  
Wilmington, DE 19899

HAND DELIVERY

Jack M. Stover, Esquire  
Buchanan Ingersoll & Rooney PC  
One South Market Square  
213 Market Street, 3<sup>rd</sup> Floor  
Harrisburg, PA 17101-2121

VIA FEDERAL EXPRESS

Todd R. Walters, Esquire  
Buchanan Ingersoll & Rooney PC  
1737 King Street, Suite 500  
Alexandria, VA 22314-2727

VIA FEDERAL EXPRESS

*/s/ John G. Day*

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John G. Day